Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in February 2003.

Supplemental Approvals

NADA Number: 137-687

This supplemental application provides for the control of certain external parasites on all finfish, shrimp, and for the control of certain fungi on finfish eggs.

Trade Name:	Formalin-F™
Ingredients:	Formalin
Sponsor:	Natchez Animal Supply Company
Approval Date:	November 25, 2002
Status:	Over-the-counter
Route:	Topical (bath treatment)
Species:	Finfish, finfish eggs, and penaeid shrimp
Drug Form:	Liquid (solution)
Concentration:	37% (by weight)
Indications:	Finfish: For the control of external protozoa (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Ichthyophthirius* spp., *Scyphidia* spp., and *Trichodina* spp.) and the monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.) Finfish eggs: For the control of fungi of the family Saprolegniaceae. Penaeid shrimp: For the control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.)
Tolerance:	Not established.
Withdrawal:	Zero days

21CFR 529.1030

ANADA Number: 200-075

This supplemental application provides for the additional use in roaster and replacement chickens (breeders and layers), roaster chickens and quail.

Trade Name:	Sacox®
Ingredients:	Salinomycin sodium
Sponsor:	Intervet, Inc.
Approval Date:	November 8, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Chickens (replacements), chickens (roasters) and quail
Drug Form:	Type A Medicated Article to make Type C medicated feeds.
Concentration:	60 grams salinomycin sodium activity per pound of Type A medicated article.
Indications:	Chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.* Quail: For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae.*
Tolerance:	*21CFR 556.592* Salinomycin: Not established. The acceptable daily intake for total residues is 0.005 milligram per kilogram of body weight per day.
Withdrawal:	Zero days

21CFR 558.550

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 200-123

This supplemental application provides for the addition of administration of oxytetracycline injectable solution to a new class, lactating dairy cattle.

Trade Name:	Maxim-200® Injection
Ingredients:	Oxytetracycline
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	November 19, 2002
Status:	Over-the-counter
Route:	Intramuscular, intravenous, or subcutaneous
Species:	Cattle
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii;* leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.
Tolerance:	*21CFR 556.500* Oxytetracycline: Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, of 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney, and 0.3 ppm in milk.
Withdrawal:	28 days

21CFR 522.1660

Suitability Petition Action

Number:	03P-0013/CP1
Sponsor:	First Priority, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Paste for Horses, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will have a different dosage form (solution) and strength from the pioneer.
Action:	Filed on January 16, 2003.

Number:	02P-0474/WDL1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to withdraw petition to file an ANADA for a generic new animal drug tiamulin hydrogen fumarate which differs from the pioneer product, Denagard™ (tiamulin) Soluble Antibiotic, Boehringer Ingelheim Vetmedica, Inc., NADA 134-644, by the following characteristics: The generic product will contain 45% tiamulin, as tiamulin hydrogen fumarate, whereas the pioneer contains 45% tiamulin hydrogen fumarate.
Action:	Filed January 31, 2003.